

AD _____

Award Number: DAMD17-98-1-8566

TITLE: A Study of Black and White Men with a Family History of Prostate Cancer

PRINCIPAL INVESTIGATOR: Roshan Batani, Ph.D.

CONTRACTING ORGANIZATION: The University of California, Los Angeles
Los Angeles, California 90095-1406

REPORT DATE: March 2001

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20010928 052

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE March 2001	3. REPORT TYPE AND DATES COVERED Annual (1 SEP 99 - 28 FEB 2001)	
4. TITLE AND SUBTITLE A Study of Black and White Men with a Family History of Prostate Cancer			5. FUNDING NUMBERS DAMD17-98-1-8566	
6. AUTHOR(S) Roshan Batani, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The University of California, Los Angeles Los Angeles, California 90095-1406 E-Mail: bastani@ucla.edu			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING-/ MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words)				
<p>The purpose of this study is to obtain information on the level of knowledge, beliefs, and screening practices of men with a family history of prostate cancer. Names of prostate cancer cases are obtained from the Los Angeles County Registry, and cases are contacted and asked to provide information on their first-degree relatives. Data gathering is being done via telephone surveys. The second year of the study has mainly focused on conducting the surveys with relatives identified by the cancer cases.</p> <p>To date, we have contacted a total of 3695 cases and have recruited 986 cases who have provided information on at least one male relative. We have completed surveys with 831 relatives. We received a no-cost extension through 2/28/02. During this final year, we will complete the validation of self-reported screening (Task 4) and final data analysis and report writing (Task 6).</p>				
14. SUBJECT TERMS Prostate Cancer, high risk men, Black, Hispanic, Asian, African American			15. NUMBER OF PAGES 24	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

TABLE OF CONTENTS

	<u>Page Number</u>
Front Cover	1
SF 298 Form	2
Table of Contents	3
Introduction & Body	4-8
Key Research Accomplishments	8
Reportable Outcomes	8
Conclusions	9
References	9
Appendices	10
1. Relative Mailed Survey Cover Letter	
2. Relative Mailed Survey	
3. PSA Screening Validation: Relative Letters	
4. PSA Screening Validation: Physician Letter	
5. PSA Screening Validation Form	

(5) Introduction

The purpose of this study is to obtain information on what high risk (a family history of prostate cancer) men know and feel about prostate cancer. The research questions to be addressed include: What do high-risk men know about prostate cancer? What is the level of psychological distress associated with knowledge of risk status? What is the personal cost-benefit ratio for these men when balancing their increased risk for the disease against the morbidity associated with treatment? What are the rates of usage of DRE and PSA in this population? What are the prevalent attitudes and beliefs in this group regarding prostate cancer screening and participation in clinical trials? Are there differences in knowledge, attitudes, behaviors, and psychological distress between different ethnic groups? What demographic, health care system, knowledge, and attitude factors are related to participation in screening and willingness to participate in clinical trials? We will use a population-based cancer registry, the Cancer Surveillance Program (CSP) of Los Angeles, to obtain a sample of prostate cancer cases diagnosed in Los Angeles County over a two year period. We will contact cases to request relative information. We will then contact relatives and ask them to participate in a brief survey, by telephone, on prostate cancer. We plan to conduct surveys with 250 African American and 250 White relatives.

(6) Body: Progress Report

The funding for this study was received at the end of October 1998, which reduced the first year of the study to 10 months, causing some of the first year's activities to extend into Year 2. In Year 2 we were able to complete all of Task 1 and get well into activities related to Tasks 2, 3 and 5. In the first 6 months of year 3, we completed Tasks 2, 3, and 5. We will focus on Tasks 4 and 6 during the no-cost extension. The following section describes some of the major accomplishments associated with each task.

Task 1

Questionnaire

Using our focus group and pilot findings, we modified and finalized our survey. It was translated into Spanish and programmed into our Computer Assisted Telephone Interviewing (CATI) database in both languages. The following domains, based on the Adherence Model, were included in the survey:

1. Medical History
2. Family History of Prostate Cancer
3. Psychological Distress
4. Past Adherence
5. Communication with Doctor
6. Demographics
7. Knowledge of Risk Factors
8. Perceived Susceptibility
9. Beliefs in Benefits vs. Costs
10. Subjective Norms
11. Fatalism
12. Social Supports
13. Barriers and Facilitators
14. Knowledge of Screening Guidelines
15. Past Participation in, Intentions & Knowledge of Clinical Trials
16. Demographics
17. Health Care Benefits & Coverage

Task 2:

Recruitment

To date, we have received a total of 14,661 prostate cancer cases from the registry (after deleting duplicates) who are still alive. Five thousand three hundred and eighteen cases were diagnosed in 1997, 4577 cases in 1998, 4248 in 1999, and 518 in 2000. As mentioned in our Year 1 Report, originally we had proposed to contact cases diagnosed in 1998 and 1999. However, we have expanded our recruitment criteria to include 1997. This turned out to be beneficial for the study overall, because reporting of the 1997 cases is much more complete than that of the 1998 cases. In addition, we have secured cases diagnosed in 2000. We continue to receive new cases from the Los Angeles Cancer Surveillance Program every two months. We have sent 4,936 letters (and if needed a second request letter) to physicians to inform them of the study. Physicians of 82 patients have recommended we not contact the cases for various reasons, and 99 cases were identified as deceased. We have updated our databases accordingly.

Cases Contacted

Although we were funded to conduct the study with only African American and White men, we explored the feasibility of expanding the study to Hispanic and Asian men as well, because of the dearth of existing information on these groups. Thus, to date we have **contacted** a total of 1054 African American cases, 700 Hispanic cases, 666 Asian cases, and 1275 White cases. Stratified random sampling has been used to select White cases in all years. Age has been used on the stratifying variable, with 20% of cases being selected from those diagnosed before age

60. We have **recruited** a total of 299 African American, 157 Hispanic, 120 Asian, and 410 White cases who have provided information on at least one male relatives between the ages of 40-75.

Relatives Recruited

We have received a total of 662 African American, 379 Hispanic, 308 Asian, and 826 White **relatives**. Of these, 475 African Americans, 250 Hispanics, 153 Asians, and 544 Whites were eligible for our study based on age, language, and no previous history of prostate cancer. A total of 1422 relatives were contacted about the study either by mail or telephone.

Due to early poor response rates among cases, we decided to assess how providing small incentives might effect response rates. We randomized the next 368 cases (diagnosed in May-June 1997) due to be contacted, into 2 groups (\$5 cash with letter; no \$5 cash). There was a moderate increase in response rates for this batch, particularly among mailed responses.

As a result of this increase in response, and our success with recruiting Hispanics and Asians, we applied for DOD Phase II funding to test the effects of incentives in our remaining cases, and extend the study to Hispanics and Asians. Unfortunately we were not funded for the additional monies requested. Therefore, we are forced to abandon incentive efforts and the recruitment of Hispanics and Asians.

Task 3

Telephone Interviews

We have conducted 831 **surveys** as of this date (264 African American, 132 Hispanic, 79 Asian, 356 Whites.) Three hundred and eighty-eight of the relatives reached either refused to participate, did not speak English or Spanish, reported having had prostate cancer, reported being either younger than 40 or older than 75, or were no longer living in the country. There was also a significant percentage of relatives (16%) that did not respond to our invitation by mail and whom we were not able to reach by telephone after 10 attempts. We adapted our telephone survey into a brief mail survey in the hope of reaching some of these hard-to-reach relatives (See Appendices 1 & 2). The mail survey contains the following items, also found in the telephone survey:

- age
- health history
- family history
- screening tests and recency of last test (if ever)
- education
- country of birth
- years in the U.S.

- ethnicity
- income
- marital status
- date of birth
- likelihood of getting screened within 12 months
- participation in clinical trials
- health insurance status

During the no-cost extension we will attempt to conduct additional telephone surveys with Hispanic and Asian subjects. This will provide valuable pilot information for future research among these groups.

Task 4

Validation of Self-Reported Screening

The UCLA Office of Protection of Human Subjects approved the validation form necessary to abstract and validate the Prostate Specific Antigen (PSA) testing dates and results for subjects. The validation form will be sent to all subjects (around 800) instead of a simple random sample as described in previous reports. This was decided by the co-investigators since the expected return rate would not be large enough from a random sample of subjects. This mailing will start in the next month, but will be continuous as more subjects are being interviewed. The validation form requires the signature of each patient to authorize release of their medical information. Reminder letters will be mailed to subjects if necessary. Once the signed validation form is returned to us, we will mail it to their noted physician in order to obtain the screening information. If necessary, follow-up calls will be placed to all physicians who do not return the form. We expect that the entire validation process will take 8-12 months. See Appendices 3-5 for the validation letters to subjects, physicians and the form.

Task 5

Interviewers

In year 1 we recruited and trained a total of 6 part-time interviewers for this project. We hired at least one interviewer to match each ethnic group. In year 2, due to the large volume of cases and relatives needed to be contacted in a timely manner (and some attrition in our interviewer staff), we hired and trained an additional 6 interviewers. Currently (middle of Year 3) we have a total of 5 interviewers remaining and are training 3 additional interviewers.

Interviewers are supervised during all day, evening, and weekend shifts. A 5% random sample of respondents are called back to verify that the interview was conducted. Interviewers are debriefed regularly.

Database Management

Our project director conducts regular checks and clean-up of our tracking databases for case and relative recruitment for accuracy and consistency of data entry and data coding. Survey data are collected using Computer Assisted Telephone Interviewing (CATI), thereby reducing interviewer error in following questionnaire skip patterns (skips are made automatically by the computer); eliminating out of range responses and missing data (a valid response is required in order to proceed to the next screen); eliminating the need for coding of most data; and providing immediate access to response frequencies at any time-point in the project. The CATI system generates daily production statistics and detailed reports of interviews completed during the session as well as refusals, scheduled call backs, and non-working phone numbers.

Task 6

Final Analysis and Report Writing

During this no cost extension period we will also do the final analysis and write the final report. This task includes items such as the following: performing item analysis of measures to ensure adequate psychometric properties, examine clustering of responses within family units, intraclass correlations among key variables, and multiple regression analyses, and examine data from the validation study to determine the extent of correspondence between self-reports and chart data.

(7) Key Research Accomplishments

- finalized the questionnaire
- translated questionnaire into Spanish
- finalized the Computer Assisted Telephone Interviewing (CATI) program
- adapted the survey questionnaire into a brief survey to mail to difficult to reach relatives
- translated the brief mail survey into Spanish
- obtained prostate cancer cases diagnosed in 1997, 1998, 1999, and 2000
- contacted physicians of cases diagnosed in 1997, 1998, 1999, and 2000
- developed tracking databases for case and relative recruitment
- trained an additional group of male and female interviewers in study objectives, content of telephone survey, basic probing techniques, cultural sensitivity and communication skills, respondent follow-up protocols and CATI operations
- recruited and completed surveys with a total of 831 eligible relatives
- received Human Subjects approval for validation protocol.

(8) Reportable Outcomes

N/A

(9) Conclusion

Our recruitment method was designed to obtain a population-based sample. Among those that are reachable, the refusal rates are reasonable. However, there are a large percentage of cases and relatives who cannot be reached due to incorrect addresses, discontinued telephone numbers, etc., thus compromising the representativeness of the sample and generalizability of findings.

(10) References

N/A

Award Number DAMD17-98-1-8566

APPENDICES

Appendices 1 & 2
Relative Mailed Survey and Cover Letter

November 17, 2000

FIELD(rfname) FIELD(rmname) FIELD(rlname)
FIELD(raddres1) FIELD(raddres2)
FIELD(rcity), FIELD(rstate) FIELD(rzip)

Dear Mr. FIELD(rlname):

We got your name from FIELD(pO_Name) who thought you might be interested in this study. We recently sent you a letter explaining our study. We are doing telephone interviews with family members of people who have had prostate cancer . Because we were unable to reach you by telephone, we are mailing you this short survey. Your answers will help us develop programs to educate people about the early detection of prostate cancer.

The survey asks about your prostate cancer risk, cancer screening, and some background information about you. Please be assured that all your answers are confidential. All information will be used only for the purposes of the study. No information which identifies you will be released without your consent.

We would really appreciate you taking the time to complete and return the survey. If you have any concerns or questions, you may call us toll-free at 1-877-278-2506.

Sincerely,



Roshan Bastani, Ph.D.
Principal Investigator

FIELD(project), FIELD(pethnic1), FIELD(PTID), FIELD(RID), FIELD(rincent)

UCLA Prostate Cancer Survey

Please be assured that there are no or wrong answers. We are interested in finding out what you feel and what you believe about cancer and other issues.

1. Please tell us your age: _____ years. (Q001)

2. Has a doctor ever told you that you have or had prostate cancer?

_____ YES (1) _____ NO (0) (Q004)

PLEASE NOTE: If you are not between the ages of 40 and 75 years of age or if you have had prostate cancer, you do not need to fill out this survey. This study is only for people who are between 40 and 75 years of age, AND who have never had **prostate** cancer. Please return the survey for our records. Your help is appreciated. Thank you.

3. Has a doctor ever told you that you have an enlarged or swollen prostate? This is also known as Benign Prostatic Hyperplasia (BHP)?

_____ YES (1) _____ NO (0) (Q008)

4. Have any of your relatives been diagnosed with cancer?

_____ YES (1) _____ NO (0) (Q011)

If YES, in the table below, please list (1) the name of your relative who has been diagnosed with cancer, (2) his/her relationship to you (for example, mother, father, sister, brother, daughter, son, aunt, uncle, cousin, grandfather, grandmother), (3) his/her age when diagnosed with cancer, and (4) the type of cancer. If you need more space, please use the back of this page.

Name of Relative (1)	Relationship (2)	Age at Diagnosis (3)	Type of Cancer (4)
i.e. James Hill	Brother	47	Prostate

The next few questions are about screening tests for prostate cancer.

5. One test that is done to find prostate cancer is the Digital Rectal Exam (DRE). For this test, a finger is inserted into the rectum to check for problems with the prostate and large bowel. Have you ever heard of a Digital Rectal Exam?

YES (1) NO (0)

(Q031)

6. Have you ever had a Digital Rectal Exam?

YES (1) NO (0)

(Q032)

Note: Please skip question 7, if you answered NO to question 6.

7. When was your most recent Digital Rectal Exam? Was it... (Q033)

- Within the last 12 months (1)
- 1 to 2 years ago (2)
- 2 to 3 years ago (5)
- 3 to 5 years ago (3)
- More than 5 years ago (4)

8. The Prostate Specific Antigen (PSA) test is a special blood test that is used to check for prostate cancer. Have you ever heard of a PSA?

YES (1) NO (0)

(Q034)

9. Have you ever had a Prostate Specific Antigen test?

YES (1) NO (0)

(Q037)

Note: Please skip question 10, if you answered NO to question 9.

10. When was your most recent Prostate Specific Antigen test? Was it... (Q039)

- Within the last 12 months (1)
- 1 to 2 years ago (2)
- 2 to 3 years ago (5)
- 3 to 5 years ago (3)
- More than 5 years ago (4)

11. Have you ever been to a urologist? A urologist is a doctor that treats disease of the kidneys, bladder, testicles, and prostate.

YES (1) NO (0)

(Q041)

The next section is for our general information only. Remember that your answers are confidential.

12. What is the highest level in school that you have completed?

(The numbers represent the years of schooling you have completed. Please circle one answer.)

(Q048)

NO SCHOOL	00							
GRADE SCHOOL	01	02	03	04	05	06	07	08
HIGH SCHOOL	09	10	11	12				
COLLEGE	13	14	15	16				
POST COLLEGE	17	18	19	20				

13. In which country were you born? _____ (Q050)

14. If you were not born in the U.S., how long have you lived in the U.S.?

(Q051) _____ Years (Q051yy) _____ Months (Q051mm)

15. Which of the following do you consider yourself to be? (Q052)

Black/African-American, *specify* _____ (1)
 Hispanic/Latino, *specify* _____ (2)
 Asian/Asian-American, *specify* _____ (3)
 Middle Eastern (8)
 Eastern European (9)
 Western European (A)
 White/Caucasian - American (4)
 American Indian/ Native American (5)
 Pacific Islander (Hawaii, Guam, Samoa, other South Pacific Island) (6)
 Mixed (Bi- or Multi-racial), *specify* _____ (7) (Q053)
 Other, *specify* _____ (V) (Q052s2)

16. Which of the following best describes your total household income, that is the yearly income of all family members living with you? We do not need the exact amount, just a range. And remember, your answer is confidential. Would you say approximately... (Q057)

Less than \$10,000 (\$0 - \$833.33/month) (1)
 \$10,000 - \$24,000 (\$833.33 - \$2000/month) (2)
 \$25,000 - \$39,000 (\$2083.33 - \$3250/month) (3)
 \$40,000 - \$54,000 (\$3333.33 - \$4500/month) (4)
 More than \$55,000 (More than \$4583.33/month) (5)

17. Are you currently married or living with someone as married?

YES (1) NO (0) (Q058)

18. What is your date of birth? (Q058A)

/ /
MM DD YYYY

19. How likely are you to ask your doctor (or nurse) about getting screened for prostate cancer? (Q088)

Very Likely (1)
 Somewhat Likely (2)
 Not Likely (3)

20. How likely are you to get a PSA blood test within the next 12 months? (Q089)

Very Likely (1)
 Somewhat Likely (2)
 Not Likely (3)

21. Have you ever participated in a clinical trial?

YES (1), *specify* _____ (Q093)
 NO (0)

22. Do you have health insurance?

YES (1), *What type of insurance?* _____ (Q083)
 NO (0)

This is the end of the survey. If you would like to be contacted for future studies, please give us a telephone number where we can reach you. Telephone # (_____. On behalf of our project, thank you for the time that you dedicated to the survey. Please send the completed to us in the enclosed envelope.

**Nilda Gallardo, Psy.D, Project Director
University of California, Los Angeles
Division of Cancer Prevention and Control Research
School of Public Health and
Jonsson Comprehensive Cancer Center
Room A2-125 CHS
Box 956900
Los Angeles, California 90095-6900**

Appendix 3
PSA Screening Validation: Relative Letters

Letter to Subjects–version 1: recent phone interview

Name

Address

Date

Dear Name:

Thank you for agreeing to let us contact your health care provider in our last telephone conversation with you. Because sometimes it is difficult for people to remember all the cancer screening tests they have had, this is the best way for us to check the specific dates.

In order to help us complete this important prostate cancer study, we need you to do the following three things:

- 1) Sign your name and date on the enclosed form.
- 2) Write in the name, address, and phone number of your health care provider.
- 3) Return this form in the postage-paid envelope and mail it to us at UCLA. We will forward it to your health care provider.

We will ask for no other information other than what is listed on the form and all the information will be kept confidential. We will send you \$5 once we receive the form from you.

Thank you again.

Sincerely,

Roshan Bastani, Ph.D.
Principal Investigator

Enclosure

Letter to Subjects–version 2: no recent phone interview

Name

Address

Date

Dear Name:

Thank you for participating in our study on men with a family history of prostate cancer and for completing our telephone survey. Because sometimes it is difficult for people to remember all the cancer screening tests they have had, we would like your permission to contact your health care provider. We will ask for no other information other than what is listed on the form and all the information will be kept confidential. We will send you \$5 once we receive the form from you.

In order to help us complete this important prostate cancer study, we need you to do the following three things:

- 1) Sign your name and date on the enclosed form.
- 2) Write in the name, address, and phone number of your health care provider.
- 3) Return this form in the postage-paid envelope and mail it to us at UCLA. We will forward it to your health care provider.

Thank you again for your continued participation in this study.

Sincerely,

Roshan Bastani, Ph.D.
Principal Investigator

Enclosure

Appendix 4
PSA Screening Validation: Physician Letter

Letter to Providers

Date

Name

Address

Dear Dr. Name:

Your patient << Patient Name >> has signed a release form for us to obtain the dates of their most recent prostate specific antigen (PSA) cancer screening test. (See enclosed form). This is an important part of our study of men with a family history of prostate cancer, in which your patient is enrolled. (See enclosed abstract.) We need this information to validate the screening information your patient gave us over the telephone.

We have enclosed \$10 to help offset the cost of obtaining this information. The enclosed signed release form is also the record abstraction form for your office staff to fill out and return to us in the postage-paid envelope. Alternatively, you or one of your staff may call and give us the information over the phone or leave it on our voice mail at the following number: (877) 278-8506. If you have any questions about this study, please do not hesitate to call me.

Thank you for your assistance.

Sincerely,

Roshan Bastani, Ph.D.
Principal Investigator

Enclosure

Appendix 5
PSA Screening Validation Form

PATIENT MEDICAL RELEASE

PATIENT:

<<Name>>
<<Address>>

Please do the three following things:

1) I authorize my licensed physician, medical practitioner, hospital, clinic or other medical related facility, or care provider permission to send Dr. Roshan Bastani at the UCLA Jonsson Comprehensive Cancer Center the dates and results of all my most recent cancer screening test listed in the box below. This authorization will be valid 24 months from the date signed unless I revoke it in writing. A photocopy of this authorization is as valid as the original.

Signature: _____ Date: _____
(<<Relative Name>>)

2) Name, address & phone number of my health care provider: 3) Mail to:
(provider with most of my medical records)

Name: _____

Dr. Roshan Bastani
Jonsson Comprehensive
Cancer Center
Box 956900
Los Angeles, CA 90095-6900

Address: _____

Phone: (____) _____

PROVIDER: (Cash reimbursement enclosed.)**Cancer Screening Tests (To be completed by health care provider and signed below)**

Test	Most Recent (Insert Date)	Reason*	Result P= positive N= negative	Next Most Recent (Insert Date)	Reason*	Result P= positive N= negative
Prostate specific antigen (PSA)						

* Reason: S= screening of asymptomatic patient or D= diagnosis of symptomatic patient

Signature: _____ Date: _____
(*Health Care Provider*)



A Study of Men with a Family History of Prostate Cancer, UCLA